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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/673,036	09/25/2003	Scott C. Mitchell	NEREUS.069A	8034

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EXAMINER

KIFLE, BRUCK

ART UNIT PAPER NUMBER

1624

DATE MAILED: 05/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/673,036

Applicant(s)

MITCHELL ET AL.

Examiner

Bruck Kifle, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 1/04; 8/04 & 9/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Claim Rejections - 35 USC § 112

Claims 1-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

i) Claim 1 is not written using proper Markush language, which requires alternative forms. Thus, in the first two lines of the claim, the phrase “and acid addition salts and pro-drug esters thereof” should be replaced by text, such as, “or an acid addition salt or prodrug ester thereof” to comply with proper Markush claiming.

ii) The nature of the “pro-drug esters” is not known. What does this look like? There is no guidance in the specification which prodrug ester is intended or what this would look like.

Arriving at a given prodrug is more than routine experimentation. Therefore, one skilled in the art would need to conduct research to understand the limitations of the claims. The term is indefinite.

iii) In claims 1, 3, 4 and 9 it is unclear where on the ring structure there is a substituent and what this substituent is. A clarification is required.

iv) In claim 5, hydrogen is listed as a possible substituent. This is unclear. A substituent is what replaces hydrogen. Deletion is suggested.

v) In claim 5, the term “cycloalkyl” is indefinite because it is not known how many atoms make up the ring and what kind of a ring is intended (monocyclic, bicyclic, spiro, fused, bridged, saturated, etc.). The term “heteroaryl” is indefinite because it is not known how many atoms are present, how many and what kind of heteroatoms are involved, what size ring is intended and how many rings are present. The term “substituted” without saying which substituents are

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intended is indefinite. One skilled in the art cannot say which substituents are permitted and which ones are not. Also, what is a substituted nitro?

vi) Regarding claims 5-7, the term "including" renders the claims indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

vii) In claim 9, the term "comprises" is open-ended. What else is intended?

viii) Claim 11 is an independent claim but does not have all of the definitions within it.

Applicants are required to either rewrite the claim as a dependent claim or insert the definition of "Formula (I)" into the claim.

ix) The differences in scope of claims 11, 12 and 17 is not understood. It appears from the specification that Applicants intention is a method of treating cancer. Appropriate deletion or clarification of the differences is requested.

Claims 1-17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification is not adequately enabling for the scope of the compounds claimed.

A single compound was isolated from a microorganism. This single compound made does NOT give a reasonable assurance that all, or substantially all of them, can be made and are useful. The claims are not drawn in terms of a recognized genus but are directed to a more or less artificial selection of substituents.

There is no reason why a claim drawn in this way should not be limited to those compounds which are shown to be both new and useful. An Applicant is not entitled to a claim for a large group of compounds merely on the basis of a showing that one compound is useful and a general suggestion of a similar utility in the others.”

Pharmacological activity in general is a very unpredictable area. Note that in cases involving physiological activity such as the instant case, “the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved”. See *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

Also, see *In re Surrey* 151 USPQ 724, regarding sufficiency of a disclosure for a Markush group, and MPEP 2164.03 for enablement requirements in cases directed to structure-sensitive arts such as the instant pharmaceutical arts. Note in *Surrey*, in which testing done on a group of homogeneous compounds having the same core was deemed NOT sufficient to support claims to various hetero groups of a much narrower range than is being claimed herein and located at only one position in the formula. The instant scope is enormous; therefore one compound within its scope is not remotely representative of such a scope. See MPEP 2164.03.

Claims 11, 12 and 17 are drawn to the treatment of cancer. The specification does not provide enablement for the treatment of cancer generally. No compound has ever been found that can treat cancers generally even though massive efforts have been directed towards this end. Since this assertion is contrary to what is known in oncology, proof must be provided that this revolutionary assertion has merits. Nearly all anticancer drugs are effective against only a limited group of related cancers. Therefore, a compound effective against cancer generally would be a revolutionary exception. Applicant is asserting that he succeeded where others have failed.

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Where extensive efforts have all failed, it is reasonable for the Patent and Trademark Office to require proof that the claimed invention actually works for this specific utility. It is well established that a utility rejection is proper when scope of enablement is not reasonably correlated to the scope of the claims. (In re Vaeck 20 USPQ2d 1439, 1444, In re Ferens 163 USPQ 609).

In re Buting 163 USPQ 689 establishes that even clinical tests showing that a compound found to be useful in the treatment of two types of cancers was not sufficient for a much broader range.

The claims are enabled for the compound of claim 10 and the use of the same to treat colon cancer, prostate cancer, leukemia and melanoma.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruck Kifle, Ph.D. whose telephone number is 571-272-0668. The examiner can normally be reached Tuesdays to Fridays between 8:30 AM and 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Bruck Kifle, Ph.D.
Primary Examiner
Art Unit 1624

BK
May 26, 2005